

## REMARKS

This is in response to the Office Action of November 18, 2003, the shortened period for response there to expiring Feb 18, 2003. Claims 1 and 8 have been amended to more particularly set forth unique features of the claimed device. In particular the claimed device has a first chamber, namely a storage chamber for storing a volume of fluid to be delivered, and a second chamber, namely an outflow chamber of a smaller capacity, for delivering a fluid to the patient at a fixed rate. Each of the storage chamber and outflow chamber, as a result of the surrounding support structure as shown in Fig. 1 and 2, has an inherent fixed maximum volume. The claimed device provides continuous and uninterrupted delivery of fluid at a predetermined rate for an extended period of time, namely hours, days or weeks while the prior art can only demonstrate the rapid delivery of a bolus of fluid, i.e., delivery of a preset dosage over a very short period of time, at most a few minutes, with delivery of the fluid interrupted, subsequent dosages being separated from said bolus delivery by extended periods of time (i.e. multiple hours).

The application comprises claims 1-9. Claims 1-9 were rejected under 35 USC §112, first paragraph in that the application does not support "providing for fluid transfer from the storage chamber to the outflow chamber at a flow rate substantially equal to the flow rate out of the outflow chamber." The examiner also has contended that applicant does not have support for the argument that applicant's device provides continuous and uninterrupted delivery of fluid for days or weeks. It is respectfully submitted that the claimed functions and features are expressly, implicitly and inherently supported by the description of the device in the specification.

The language objected to has been amended to read -- providing for fluid transfer from the storage chamber to the outflow chamber at a flow rate substantially equal to or greater than the flow rate out of the outflow chamber.-- However, it is respectfully submitted that the prior language does not constitute new matter and is fully supported by the specification. Because the storage chamber is always maintained at a pressure greater than the pressure in the outflow chamber, for example 1-10 psi in the outflow chamber and over 20 psi in the storage chamber (page 5, lines 18-19), and the outflow chamber has a finite fixed maximum volume, flow out of the outflow chamber is restricted in a controlled manner, and the fluid flows from the storage chamber to the outflow chamber at a rate equal to or greater than the rate at which the fluid flows out of the outflow chamber. In particular, when the

outflow chamber is fully expanded flow into that chamber must be equal to the flow out of that chamber. Only when said out flow chamber is not fully expanded does flow into it exceed outflow. In operation, the outflow chamber is always substantially at its maximum volume and therefore inflow will be equal to outflow. Because valve 140 opens and closes as the pressure of the outflow chamber fluctuates around the pressure set point the result is a "steady, pressure regulated flow of fluid from the storage container 120 into the outflow chamber 130" (page 9, lines 28-30). It is inherent in the described and claimed design that the rate of fluid flow from the storage chamber to the outflow chamber must be substantially equal to or, during filling operation, greater than the flow out of the outflow chamber and can not, over each of the periods that valve 140 is open, be less than the flow out of the outflow chamber. The arrangement of the valves and the selection of the pressure differential provides "a steady, regulated flow of fluid from the storage chamber 20 to the outflow chamber 30." (page 5, lines 25-26) As long as the storage chamber contains fluid the outflow chamber will always be full and will always continuously deliver fluid at the desired preset rate; it is a constant flow pump and not an intermittent or bolus pump.

In the examples, based on the exemplary dimensions of delivery tubing used with the output chamber, a flow of 0.5ml/hr to 4.0 ml/hr results (page 7, lines 15-20). An exemplary pump arrangement with a 200ml storage chamber (page 8, line 20) operating at a 6psi set point (page 8, line 31 – page 9, line 5) continuously delivers fluid for 400 hours( 200ml divided by 0.5ml/hr) to 50 hours (200ml divided by 4ml/hr). However, typical devices hold up to 500ml (page 8, line 21) which will provide, at 6psi and with the feed catheters described, from 125 hours to 1000 hours (5 to 40 days) of continuous, uninterrupted feed of fluid without refilling the storage container. This operation of the pump is expressly, implicitly and inherently described in the specification such that one skilled in the art would readily recognize that the device provides continuous, uninterrupted delivery of fluid for an extended period of time constituting days or weeks.

While the claims have not been rejected based on Arzbaeher, US Patent 5,607,418, said reference is once more cited as demonstrating continuous delivery of fluid. This is clearly an erroneous recitation of the teachings of Arzbaeher. Arzbaeher shows a drug pump which has a preset delivery mass flow rate when both flow means 30 and 35 are open. In order to accomplish this, the flow rate of fluid from the outer (storage) chamber 21 into the inner (output) chamber 26 is restricted to a flow rate of 1/10 to 1/150 of the flow rate of the

fluid from the inner chamber to the catheter 14 and then to the patient. Arzbaeher delivers fluid to the patient from the outflow chamber at a high flow rate in short bursts, known as a bolus pump. It then refills the out flow pump at a very slow rate, compared to the outflow rate. It is not capable of delivering, or intended to deliver, fluid from the storage chamber to the output chamber at the same or greater rate and therefore can not anticipate or render obvious applicant's claimed invention. Arzbaeher discloses a totally different device that operates in a totally different manner to give a totally different end result.

The Arzbaeher drug pump is not a pump for the continuous, uninterrupted delivery of a drug over an extended period of time. It is a pump which rapidly dispenses its contents (delivery of a bolus) and then is very slowly refilled. The maximum flow rate to the patient is controlled by the pressure of the fluid in the outer (storage) chamber and the flow rate allowed by the flow restrictor between the outer chamber and the inner chamber. The flow restrictor between the inner chamber and the catheter controls the flow rate at which the bolus can be delivered to the patient. That output flow rate is 10 times to 150 times greater than the flow rate of fluid into the inner (output) chamber (ie. flow from the storage chamber to the output chamber). In order for the Arzbaeher pump to operate the inner (output) chamber must have a return bias force built into the chamber in order for it to refill after the fluid has been dispensed from that chamber. If this return bias force is not present, the chamber would not refill.

Applicant must take issue with the examiners characterization of Arzbaeher as showing a continuous deliver drug pump. One skilled in the art would clearly recognize that, based on the teachings of Arzbaeher, that patent is directed to a bolus pump for delivered discrete quantities of a fluid over a very short time period separated by an extended period of time necessary to refill the output chamber. For example, the Arzbaeher drug pump is described as delivering 4ml at a rate of 0.4ml/min, more specifically 4ml over a period of 10 minutes. The refill rate of the output chamber is 8ml/day or 0.005ml/min (Col 4, line 45). It is capable of delivering only a 4ml bolus in no more then 10 minutes followed by an interruption of 12 hours where no fluid is delivered. In contrast, applicant's claimed device delivers 0.5ml - 4.0ml/hr (0.008-0.07ml/min) over an extended period of time, clearly significantly in excess of 10 minutes, and refills at substantially the same rate, or a greater rate, as fluid flows from the large storage chamber to the output chamber. Further, because the storage chamber can be refilled from an external source while the output chamber is

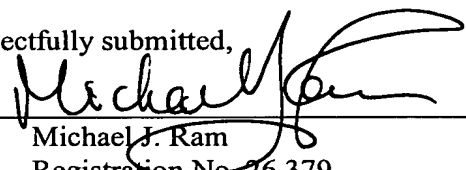
delivering fluid to the chamber, the claimed device can delivery drug continuously and uninterrupted for as long as desired by the physician. The difference between these devices is not a mere variation of a prior disclosed system; it is a totally different and unique device which operates in a totally different manner not previously disclosed or suggested to provide a totally different and unexpected result. In Arzbaeher, a bolus is delivered from the outflow chamber depleting the outflow chamber contents. Flow to the patient then ceases while the outflow chamber refills, followed by another bolus delivery. The claimed device will continuously deliver fluid for as long as there is fluid in the storage chamber – the output chamber is never empty. The Arzbaeher output chamber fills and empties repeatedly and only delivers a dosage when the output chamber is full, even if there is fluid in the storage chamber.

Claims 1-9 remain in the application. It is respectfully submitted that these claims are patentable, fully supported by the Specification and not shown nor suggested by the cited reference. It is requested that the claims be found to be patentable and a Notice of Allowance be issued. Should the Examiner have further objections to the claims or basis for rejection, it is respectfully requested that the undersigned be telephoned at 805-373-0060 so that suitable allowable claim language can be proposed and the prior art objections can be addressed to place the application in form for allowance.

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Respectfully submitted,

By:

  
Michael J. Ram  
Registration No. 26,379  
Attorney for Applicant(s)

KOPPEL, JACOBS, PATRICK & HEYBL  
555 St Charles Drive, Suite 107  
Thousand Oaks, CA 91360  
Phone (805) 373-0060  
Fax (805) 373-0051  
CN/PATENT/AMEND00926004.2-11-04

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